HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 1001 Health Care
SPONSOR(S): Insurance & Banking Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:** SB 1534

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Insurance & Banking Subcommittee		Salzverg	Cooper

SUMMARY ANALYSIS

Current law requires the Agency for Health Care Administration (AHCA) to establish a preferred drug list (PDL) for the state's Medicaid Managed Assistance Program (MMA), in order to control drug expenditures. Recommendations for inclusion on the PDL are made by the Pharmaceutical and Therapeutics Committee (P&T Committee), based on clinical efficiency, safety, and costs. Current law requires the P&T Committee to review drugs newly approved by the FDA within three months of public availability, but does not mandate coverage of such drugs until they are reviewed. The proposed committee substitute (bill) requires MMA plans to include newly-approved drugs on the PDL until the P&T Committee has reviewed them for inclusion. The bill also requires that the PDL include at least two products in a therapeutic class whenever feasible. Additionally, the bill requires MMA plans to continue to cover drugs that they remove from their PDL, for recipients who have statements from their prescribers indicating continued use of the drug is medically necessary.

The bill also makes changes to Medicaid and commercial health insurance plans regarding step-therapy protocols, payment of claims, and notice requirements regarding preferred providers.

Step-therapy pharmaceutical programs are intended to contain costs for prescribed medications, by requiring providers to prescribe lower-cost drugs before trying other, usually more expensive, drugs. Many step-therapy programs allow prescribing providers to request an override of the step-therapy protocols. The bill requires insurers to provide prescribing providers a "clear and convenient process" to request an override, which must be granted within 24 hours of a completed request if the prescribing provider, based on sound clinical evidence, feels the protocol will be ineffective or is likely to cause an adverse effect to the insured.

Current law requires health maintenance organizations (HMOs) and health insurers to provide a grace period after an insured or subscriber fails to pay renewal premiums and must temporarily authorize claims for treatment sought during this grace period. If the insured/subscriber ultimately does not pay renewal premiums, the HMO or insurer may deny the claims. The bill amends current law to provide that HMOs and insurers may not retroactively deny a claim if they have (a) verified eligibility of an insured's plan at the time of treatment and received an authorization number or (b) if they have provided the insured with an identification card, which serves as proof of eligibility at the time of treatment.

Additionally, the bill requires insurers who offer coverage for services of a preferred provider to post a link to the insurer's website containing a list of preferred providers and to update the list within 24 hours of any change.

The fiscal impact on the state is currently indeterminate, but likely significant. AHCA has determined that the provisions related to MMA programs will likely cause them to incur costs of authorizing additional medications that previously would not have been approved. The State Group Health Insurance Program will also likely incur increased costs for medical claims. Insurers may incur increased costs in complying with the provisions of this bill. Such cost increases will be borne by employers and policyholders.

The bill takes effect July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

This Proposed Committee Substitute (PCS) addresses issues relating to managed care plans providing health care services to Medicaid recipients as well as issues relating to managed care organizations and health insurers serving commercial clients.

Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds. AHCA delegates certain functions to other state agencies, including the Department of Children and Families, the Agency for Persons with Disabilities, and the Department of Elder Affairs. For Fiscal Year 2014-15, the federal government will pay for 59.10 percent of the costs of the program and the state must pay the balance.[1] For Fiscal Year 2014-15, Florida's Medicaid program is estimated to have 3.7 million enrolled recipients and $22.3 billion in total spending with $5.7 billion in general revenue.[2]

The structure of each state's Medicaid program varies, but what states must pay for is largely determined by the federal government as a condition of receiving federal funds. Federal law sets the amount, scope, and duration of services offered in the program, among other requirements. These federal requirements create an entitlement that comes with constitutional due process protections.

The federal government sets the minimum mandatory benefits to be covered in every state Medicaid program. These benefits include physician services, hospital services, home health services, and family planning.[3] States can add benefits, with federal approval. Florida has added many optional benefits, including prescription drugs, adult dental services, and dialysis.[4]

Florida Medicaid is the second largest single program in the state, behind public education. Florida's program is the 4th largest in the nation, and the 5th largest in terms of expenditures. Florida's Medicaid costs have increased significantly since its inception, due to substantial eligibility expansion as well as the broad range of services and programs funded by Medicaid expenditures.

Medicaid Prescribed Drug Benefits

Medically necessary prescription drugs are an optional Medicaid service under federal law, which Florida chooses to cover.[5]

For Medicaid reimbursement, a drug must be included in a rebate agreement with the U.S. Department of Health and Human services, it must be medically necessary for the patient, and must either be prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in accordance with Section 1927(k)(6) of the Social Security Act, or prior authorized by a qualified clinical specialist approved by AHCA.[6]

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[1] Social Services Estimating Conference, Medicaid Caseload and Expenditures, December 17, 2013, available at: http://edr.state.fl.us/Content/conferences/medicaid/index.cfm (last viewed March 22, 2014)
[2] Id.
[3] S. 409.905, F.S.
[4] S. 409.906, F.S.
[5] 42 U.S.C. 1396d; s. 409.906, F.S.
[6] AHCA, Florida Medicaid Prescribed Drugs Coverage Limitations and Reimbursement Handbook, June 2012, p. 3-ii, available at http://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/Prescribed_Drug_Services_Handbook_Publications_V1.pdf (last viewed March 22, 2014), incorporated by reference in Fla. Admin. Code Ann. r. 59G-4.250 (2012).

Florida Medicaid processes over 1.3 million drug claims per month in the fee-for-service program.[7] In Fiscal Year 2013-2014, the legislature appropriated over $1.5 billion for the Medicaid prescription drug benefit. Federal rebates and state supplemental rebates account for 52.6% of the cost of drugs in the fee-for-service Medicaid program; general revenue accounts for covers 20.3% and federal matching funds cover 27%.[8]

The Legislature has enacted and AHCA has implemented many provisions to control the utilization and expense of the prescribed drug benefit, and reduce fraud and overpayments in the program. These include pharmacy provider standards, statutorily-defined pricing, a prescribing pattern review panel, a pharmacy lock-in program, counterfeit-proof prescription pads, a behavioral drug management system, state supplemental rebates, prior authorization, step-therapy, and a preferred drug list.[9]

Medicaid Preferred Drug List

Section 409.912(37), F.S., requires AHCA to establish a preferred drug list to control drug expenditures.[10] Recommendations for inclusion on the preferred drug list (PDL) are made by an 11-member Pharmaceutical and Therapeutics Committee (P&T Committee) of physicians, pharmacists, and a consumer representative, appointed by the Governor.[11] The P&T Committee is required to base its PDL recommendations on the clinical efficacy, safety and cost-effectiveness of a product.[12]

AHCA is authorized to negotiate state supplemental rebates with manufacturers (in addition to the HHS-negotiated federal rebate), and agreement to pay the minimum statutory rebate percentage guarantees the P&T Committee will consider the drug for inclusion on the PDL; however, it does not guarantee placement on the PDL. The PDL must include at least two drugs for each therapeutic class, and the P&T Committee must review each class every 12 months, if feasible.[13]

AHCA is required to ensure that the P&T Committee reviews a drug newly-approved by the U.S. Food and Drug Administration (FDA) *under a priority review classification* at the next meeting following three months of its public availability.[14] The FDA has two review classifications, to distinguish between drugs that demonstrate the potential to improve or prevent a serious or life-threatening condition from those that do not:[15]

- Priority review applies to drugs that treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions compared to available therapies. The FDA decides these applications within 6 months.
- Standard review applies to drugs that do not meet the priority review designation criteria. The FDA decides these applications within 10 months.

The AHCA Secretary makes the ultimate decision as to which drugs are placed on the PDL.

Medicaid Prescription Drug Prior Authorization

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[7] AHCA, Medicaid Prescribed Drug Program Spending Control Initiatives for Quarters ending December 31, 2013 and September 30, 2013, p. 2., available at http://ahca.myflorida.com/medicaid/prescribed_drug/pdf/SFY_2012-13_Q1-Q2_FINAL.pdf (last visited March 22, 2014).
[8] AHCA, Prescribed Drug Program Spending report, supra note 7, p. 6.
[9] Pursuant to s. 409.912(37)(a)17.c, F.S., AHCA issues a quarterly report on the spending control initiatives for the prescribed drug benefit.
[10] Florida Medicaid Preferred Drug List, available at: http://www.ahca.myflorida.com/Medicaid/Prescribed_Drug/pharm_thera/fmpdl.shtml (last viewed March 22, 2014).
[11] S. 409.91195, F.S.
[12] S. 409.91195(8), F.S.
[13] Ss. 409.912(37), 409.91195(4), F.S.
[14] S. 409.91195(7), F.S.
[15] U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Review Designation Policy, MAPP 6020.3 Rev. 2, July 2013, available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffPoliciesandProcedures/ucm082000.pdf (last viewed March 23, 2014).

Generally, reimbursement for PDL drugs is automatically authorized. Drugs which are not on the PDL must be prior authorized.[16] Non-PDL drug prior authorization includes a "step-therapy" or "fail-first" requirement which may vary by drug. This requires the patient to have unsuccessfully tried PDL medications in the same class in the last 12 months. However, Medicaid patients can bypass the step-therapy requirement and obtain prior authorization for a non-PDL drug if the prescribing physician provides documentation indicating that the non-PDL drug is medically necessary because:

- No PDL drug is an acceptable clinical alternative;
- The PDL drugs have been ineffective in treating the patient's particular disease;
- The PDL drugs are likely to be ineffective, based on this particular patient's characteristics; or
- The number of doses has been ineffective.[17]

Separate from the non-PDL prior authorization requirement, Florida Medicaid imposes a clinical prior authorization requirement for a limited list of drugs:

- When prescribed for an indication not approved in FDA labeling;
- To ensure compliance with certain clinical guidelines; or
- If the product has the potential for overuse, misuse, or abuse (such as Oxycontin).[18]

AHCA must respond to a request for prior authorization within 25 hours, and must grant a 72-hour supply if the response takes longer than 24 hours.[19]

Currently, Medicaid managed care plans may use AHCA's PDL and prior-authorization rules for their prescription drug coverage programs, or may develop their own preferred drug lists and prior authorization and step-therapy or fail-first processes. These processes must be approved by AHCA.[20]

Statewide Medicaid Managed Care

In 2011, Florida established the Statewide Medicaid Managed Care (SMMC) program as Part IV of Chapter 409, F.S. The SMMC requires AHCA to create an integrated managed care program for Medicaid enrollees to provide all the mandatory and optional Medicaid benefits for primary and acute care. Each Medicaid recipient will have one managed care organization to coordinate all health care services, rather than various entities as in the current Medicaid program. This comprehensive coordinated system of care was successfully implemented in a 5-county Medicaid reform pilot program which began in 2006.

The SMMC program has two components: the Long-term Care Managed Care Program and the Managed Medical Assistance (MMA) Program. The MMA program provides primary and acute medical assistance and related services. On December 28, 2012, AHCA released an Invitation to Negotiate (ITN) to competitively procure managed care plans on a statewide basis for the MMA program.[21] AHCA subsequently selected health maintenance organizations and provider service networks via the competitive procurement. On February 6, 2014, AHCA executed contracts with the MMA managed care plans.[22]

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[16] AHCA Provider Handbook, supra note 7 at 3-vi. Oral contraceptives and HIV/AIDS anti-retroviral agents are not subject to the PDL process and are not subject to prior authorization. AHCA Provider Handbook supra note 6 at 3-xv.
[17] S. 409.912(37)(a)16., F.S.; AHCA Provider Handbook, supra note 6 at 3-vi.
[18] AHCA Provider Handbook, supra note 6 at 3-xv.
[19] S. 409.912(37)(a)1.a., b., F.S.
[20] AHCA, Legislative Bill Analysis, HB 1001, Feb. 14, 2014, p. 2.
[21] Id.
[22] AHCA Invitation to Negotiate, *Statewide Medicaid Managed Care*, *Addendum 2* Solicitations Number: AHCA ITN 017-12/13; Feb. 26, 2013, available at: http://myflorida.com/apps/vbs/vbs_www.ad.view_ad?advertisement_key_num=105774 (last visited March 22, 2014); AHCA Invitation to Negotiate, *Statewide Medicaid Managed Care*, Solicitation Number: AHCA ITN 017-12/13, Dec. 28, 2012, available at: http://myflorida.com/apps/vbs/vbs_www.ad.view_ad?advertisement_key_num=105774 (last visited March 22, 2014).

AHCA will begin implementing the MMA program in selected regions on May 1, 2014 with the last regions being implemented on August 1, 2014. The program must be fully implemented in all regions by October, 2014, as directed in s. 409.971, F.S.

MMA Prescribed Drug Benefits

The MMA contracts require the managed care plans to use the AHCA PDL for the first year of operation, to ensure a smooth transition of recipients and coverage.[23] After the first year, AHCA has the option of requesting that the MMA plans develop their own preferred drug lists and submit them for AHCA's consideration.[24] The MMA plans must use AHCA's prior-authorization rules for their prescription drug coverage programs; unless they receive permission from AHCA to develop their own prior authorization and step-therapy or fail-first processes.[25] The plan's prior authorization and step-therapy or fail-first processes cannot be more restrictive than those used by AHCA.

Effect of the Proposed Committee Substitute (Bill)

Medicaid

Managed care plans participating in MMA would have to comply with the provisions of the bill that specifically relate to the MMA program and the provisions that generally relate to managed care plans. Additionally, AHCA would have to amend the MMA contracts where the current contract provisions conflict with the provisions of the bill.

Override of Step-Therapy or Fail-First Protocols

The bill amends Medicaid law to create a less stringent override procedure for step-therapy and fail-first protocols than required under current Medicaid law and in the MMA contracts. The bill allows an override when the proscribing provider determines, or believes, based on clinical or medical evidence that the preferred treatment would be ineffective or cause harm. Additionally, the bill allows the prescriber to determine the length of time the Medicaid recipient uses the step-therapy drug. Under the bill, the prescribing provider can "deem the treatment clinically ineffective" and the recipient will automatically be granted an override.

Newly-Approved Drugs

Current law requires the Medicaid P&T Committee to review drugs that are newly-approved under a priority review classification by the FDA within three months of public availability, and does not require Medicaid to cover them without prior authorization until reviewed.[26] The bill requires the MMA plans to include, through prior authorization, newly-approved drugs before the plans have reviewed the drug for inclusion in their formularies – regardless of the FDA review classification. This both expands the mandatory P&T Committee review to include drugs which *do not* improve or prevent a serious or life-threatening condition, and mandates that they be covered without prior authorization until considered by the P&T Committee. The bill requires the review of the new drug to take place at the next meeting of a plan's formulary committee following three months of distribution of the drug to the general public, which is consistent with current law.

Drugs Removed from the PDL

[23] Model Agreement, Attachment II, Exhibit II A, Medicaid Managed Medical Assistance Program, Agency for Health Care Administration, February, 2014, available at http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#mmaplans (last viewed March 23, 2014).
[24] Id.
[25] Id.
[26] S. 409.91195(7), F.S.

The bill amends Medicaid law to require the MMA plans to continue to cover drugs that they remove from their formulary or PDL for recipients who have written statements from their prescribers indicating the drugs continue to be medically necessary.

Retroactive Claim Denial

The bill amends s. 641.3155, governing prompt payment of claims by HMOs, to prohibit a HMO that has verified the eligibility of a subscriber at the time of treatment and has provided an authorization number from retroactively denying a claim because of subscriber ineligibility. Currently, the Medicaid MMA contracts require the MMA plans to comply with s. 641.3155, F.S.[27], so changes to this section would be applied to MMA HMOs.

Identification Cards

Current Medicaid rules and contracts require providers to verify recipient eligibility, and HMO enrollment if applicable, prior to submitting a claim.[28] The rules specifically provide that possession of a Medicaid identification card "does **not** mean a recipient is eligible for Medicaid services".[29] Medicaid recipients may move in and out of eligibility often, and old Medicaid identification cards are reactivated when they become eligible again. A Medicaid identification card is not a reliable indicator of eligibility, and relying on them could result in claim denial if the recipient is no longer eligible.

The bill amends s. 641.3155, governing HMOs, to prohibit a HMO from retroactively denying a claim because of subscriber ineligibility if the HMO provided the subscriber with an identification card which, at the time of service, identifies the subscriber as eligible to receive services. This provision would also apply to Medicaid MMA plans. The bill would require Medicaid coverage of claims for people who were not eligible at the time of service, based on possession of a non-current identification card, with no obligation for the provider to verify eligibility.

Commercial plans

The bill also revises current law regarding payment of claims, step therapy pharmaceutical protocols, and contracts for health insurers and health maintenance organizations.

Payment of Claims and Grace Periods under Florida Law

Part VI, ch. 627, F.S., relates to health insurance policies. Section 627.608, F.S., requires that every health insurance policy by commercial health insurers provide a grace period after an insured fails to pay renewal premiums on time, so that the policy stays in force throughout the grace period and the policyholder can remain eligible for service during that grace period. Regardless whether the insurer reserves the right to refuse renewal, each policy must include a provision that the insured has a 7-day grace period for a weekly premium policy, a 10-day grace period for a monthly premium policy, or a 31-day grace period for all other policies, and the insured may pay the renewal premium during the grace period.[30]

For HMOs, s. 641.31(15), F.S., requires that all health maintenance contracts, certificates, and member handbooks contain a provision that the contract has a grace period of no less than 10 days, and the

[27] Model Agreement, Attachment II, Medicaid Managed Medical Assistance Program, Agency for Health Care Administration, February, 2014, available at http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#mmaplans (last viewed March 23, 2014).
[28] AHCA, Florida Medicaid Provider General Handbook, July 2012, p. 1-27, 3-5, 3-14, available at http://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/GH_12_12-07-01_Provider_General_Handbook.pdf (last viewed March 22, 2014), incorporated by reference in Fla. Admin. Code Ann. r. 59G-5.020 (2012).
[29] Id. at 3-3.
[30] If the insurer does reserve the right to refuse renewal, the grace period does not apply if the insurer has delivered or mailed written notice of the insurer's intent of non-renewal to the insured's last address at least 30 days before the premium due date. Section 627.608, F.S. It has been represented to staff that some large insurers, such as Florida Blue, have adopted a 31-day grace period for all policies.

contract will stay in force during the grace period and any premium that was not paid on time may be paid during the grace period.[31]

If a patient seeks treatment during the grace period and a provider seeks prior authorization or seeks verification or of a patient's insured status during such time, the prevailing view is that an insurer cannot take any action other than following the policy terms, and must affirmatively respond that the patient is insured. Accordingly, an insurer would be violating the grace period statute if an insurer either disclosed to the provider that the patient was in a grace period and had yet not paid his or her renewal premium or denied the authorization. In essence, these statutes require HMOs and health insurers to give temporary authorizations during the pendency of the grace period. If the patient ultimately fails to pay his or her renewal premium by the end of the grace period, the insurer may deny the claim, which places providers in the position of collecting payment directly from the patient for any care rendered during the grace period.

Payment of Claims and Grace Period under Federal Law

The federal regulations implementing the Affordable Care Act also contain a grace period for enrollees in qualified health plans (QHPs) and federally facilitated exchanges.[32] *QHPs* are health plans that are subject to certain requirements related to marketing, choice of providers, plan network, essential benefits, and other features, and must be accredited by HHS and licensed by each state in order to provide coverage in those respective states. *Federally-facilitated marketplaces* are established and operated by the U.S. Department of Health and Human Services for states that did not elect to form and operate their own marketplaces. However, states may elect to perform use federal government services for reinsurance programs and Medicaid and CHIP eligibility assessments or determinations.

The CMS regulations provide that for enrollees in a qualified health plan who receive an advance premium tax credit, they remain eligible for services for a 90-day grace period.[33] In addition, the CMS regulations require that QHP issuers pay providers for services rendered during the first 30 days of the grace period, and those payments in the first month are not subject to recoupment. However, for the second and third months of the grace period, the QHP is permitted (but not required) to "pend" claims for services, by deferring payment until the patient pays the renewal premium. If the enrollee ultimately fails to pay his or her renewal premium by the end of the grace period, the QHP issuer may deny the claims for services rendered.[34]

As is the case with HMOs and commercial health insurers, this grace period process places providers in the position of collecting payment directly from the patient for any care rendered during the final 60 days of the grace period, if the patient ultimately fails to pay the premium.

Retroactive Denial of Claims

Sections 627.6131 and 641.3155, F.S., contains required timeframes for health insurers and HMOs, respectively, to pay claims and sets forth provisions for disputed and overdue claims. These provisions cannot be waived, voided, or nullified by contract.[35] Both statutes also prohibit health insurers and HMOs from retroactively denying a claim because of an insured's or subscriber's ineligibility more than one year after the date of payment of the claim.

Effect of the Bill Relating to Payment of Claims

[31] As with commercial health insurers, it has been represented to staff that many HMOs have also adopted a 31-day grace period for all health maintenance contracts. Additionally, s. 641.341(15)(b), F.S., provides that this minimum 10-day grace period for health maintenance contracts applies to group health maintenance contracts only.
[32] 45 C.F.R. Parts 155, 156, and 157. *See* 45 C.F.R. § 155.20 for definitions of qualified health plans and federally facilitated exchanges; *see also* "Building the Health Insurance Marketplace," at http://www.ncsl.org/research/health/american-health-benefit-exchanges.aspx (last viewed March 23, 2014).
[33] The enabling legislation requires QHPs to "allow a three-month grace period for non-payment of premiums before discontinuing coverage." 42 U.S.C. §18082(c)(2)(B)(iv).
[34] 45 C.F.R. §156.270, relating to termination of coverage for qualified individuals.
[35] Sections 627.6131(10) and 624.3155(9), F.S.

The bill amends ss. 627.6131(11) and 641.3155(10), F.S., to add that health insurers and HMOs, respectively, may not retroactively deny a claim because of an insured's or subscriber's ineligibility, if the health insurer or HMO has (a) verified the eligibility of an insured's or subscriber at the time of treatment and has provided an authorization number, or (b) provided the insured or subscriber with an identification card, as provided for in s. 627.642(3) that at the time of service identifies the insured or subscriber as eligible to receive services.

It is unclear whether the bill's provision that the presentation of an authorization number or an identification card will prevent an HMO or health insurer from retroactively denying a claim because of insured or subscriber ineligibility. First, the grace period statutes discussed above require HMOs and health insurers to give temporarily authorizations for treatment sought during the grace period, but allows HMOs and health insurers to deny payment if the patient ultimately pays to pay the premium at the end of the grace period and is ultimately ineligible. The bill's prohibition on retroactive denial, when a provider has relied on a temporary authorization, would in effect require health insurers and HMOs to authorize payment of claims even for ultimately ineligible patients.

Secondly, s. 627.642(3), F.S., which specifies minimum requirements of an identification card for a health insurance policy, currently does not require that the identification card identify whether the insured or subscriber is eligible. The statute only requires items such as the name of the insurer and the contract holder, type of plan, the member identification number, and contact phone numbers or electronic addresses for authorization, admission certifications, and for the provider to verify benefits and information to estimate patient financial responsibility. It is unknown how many insurers and HMOs include information, beyond what is statutorily required, on the identification cards that would enable providers to verify a patient's eligibility at the time of service and from the face of the cards.

Step-Therapy Pharmaceutical Protocols[36]

Managed care organizations and health insurance plans are increasingly adopting step-therapy pharmaceutical programs in an effort to contain costs and assess risks regarding prescribed medications. These programs typically require providers to prescribe lower-cost drugs before trying other, usually more expensive and sometimes riskier, drugs used for the same treatment. Generally, step-therapy requires a patient to try a first-line medication within a drug class, often using a generic alternative, prior to receiving coverage for a second-line or back-up medication, usually a branded product.[37]

Organizations and plans which have implemented step-therapy programs have also established specific procedures allowing patients access to second-line drugs. Procedures vary, but many programs provide coverage of back-up drugs if:

- the patient has already tried the first-line drug and the medication was unsuccessful;
- the patient cannot take the generic drug (for example, because of an historic allergy); or
- the physician decides for medical reasons the patient needs a brand name or second-line medication.

If any of these situations apply, many managed care organizations or health insurers allow physicians to request an override which, if granted, allow the patient to receive the back-up medication.[38] Many step-therapy programs also allow patients to use a second-line medication if recent insurance claims

[36] Although "fail-first" is sometimes used, the clinical and academic literature on this topic, as well as the managed care industry, refer to these programs as "step-therapy."
[37] Mark,T. et al., "The Effects of Antidepressant Step Therapy Protocols on Pharmaceutical and Medical Utilization and Expenditures," *The American Journal of Psychiatry*, 2010: 167:1202-1209 available at http://ajp.psychiatryonline.org/article.aspx?articleid=102459 (last viewed on March 22, 2014). *See also* "Definition of Step Therapy," at http://www.medterms.com/script/main/art.asp?articlekey=40302 (last viewed on March23, 2014), and "Pharmacy Programs' Step Therapy: What is it?" at http://www.jmbhealthconnect.com/276 (last viewed on March 23, 2014).
[38] "Frequently Asked Questions – Step Therapy" available at: https://member.express-scripts.com/.../StepTherapyFAQs (last viewed on March23, 2014).

are found for the first-line drug, or if members recently obtained a prescription for the second-line drug.[39]

Effect of the Bill Relating to Step-Therapy Protocols

The bill creates new provisions regarding step-therapy protocols implemented by health maintenance organizations or health insurers. The bill provides that when medications for the treatment of a medical condition are restricted for use by an insurer by a step-therapy or fail-first protocol, the prescribing provider must have access to a "clear and convenient process" to request an override of the protocol from the HMO or health insurance issuer. The HMO or health insurer must grant an override of the protocol within 24 hours under the following circumstances:

(a) The prescribing provider recommends, based on sound clinical evidence, that the preferred treatment required under the step-therapy or fail-first protocol has been ineffective in the treatment of the insured's disease or medical condition; or
(b) Based on sound clinical evidence or medical and scientific evidence:
    1. The prescribing provider believes that the preferred treatment required under the step-therapy or fail-first protocol is expected or likely to be ineffective based on known relevant physical or mental characteristics of the insured and known characteristics of the drug regimen; or
    2. The prescribing provider believes that the preferred treatment required under the step-therapy or fail-first protocol will cause or is likely to cause an adverse reaction or other physical harm to the insured.

The effect of these provisions is that a prescribing provider must be granted an override as long as in his or opinion, based on sound clinical evidence (which is undefined) the first line drug has been ineffective in the treatment of the insured's disease or medical condition, even if that runs counter to the rulings of the FDA, peer reviewed literature, and the assessment of the medical directors and medical and pharmaceutical review committees of the HMO or health insurer.

The bill also states that if the prescribing provider allows the patient to enter the step-therapy or fail-first protocol recommended by the insurer, the duration of the step-therapy or fail-first protocol may not exceed a period deemed appropriate by the provider. If the prescribing provider deems the treatment clinically ineffective, the patient is entitled to receive the recommended course of therapy without requiring the prescribing provider to seek approval for an override of the step-therapy or fail-first protocol.

The effect of this provision would appear to allow a physician to circumvent the procedures delineated above in (a) and (b) by enabling the provider to agree to a patient's participation in the step-therapy protocol and then immediately discontinuing the medication and prescribe a drug without requiring an override.

Notice Requirements Regarding Preferred Providers

Current law requires any insurer offering coverage for the services of a preferred provider to provide each policyholder with a current list of preferred providers. Additionally, current law requires the insurer to make the current list available for the public during regular business hours at the insurer's principal office.[40]

Since this law went into effect, the creation of the Internet has transformed the sharing of information. Insurers in Florida routinely update the list of their preferred providers and make the list available on their website. Insurers update their list regularly (usually within 24-48 hours), although the frequency of such updates is not currently mandated by statute. It is common practice for insurers to also list a

[39] *Supra* fn. 36 (Mark, T. et al)
[40] S. 627.6471(2), F.S.

phone number on the list for policyholders to call with questions, including inquiries regarding the availability of certain providers and service.[41]

Effect of the Bill Relating to Notice Requirements

The bill amends s. 627.6471(2), F.S., requiring any insurer offering coverage for the services of a preferred provider to post a link on the insurer's website containing the list of preferred providers. The bill requires insurer's to reflect on their website, any changes to the list within 24 hours. It is unclear whether the online list will need to be updated within 24 hours of any change to any of the contracts with preferred providers, or may be updated by the end of the next day.

B. SECTION DIRECTORY:

Section 1: Amends s. 409.967(2)(c), F.S., relating to managed care plan accountability.

Section 2: Amends s. 627.6131(11), F.S., relating to payment of claims.

Section 3: Creates s. 627.6466, F.S., relating to fail-first protocols.

Section 4: Amends s. 627.6471(2), F.S., relating to contracts for reduced rates of payment; limitations; coinsurance and deductibles.

Section 5: Amends s. 641.3155(10), F.S., relating to prompt payment of claims.

Section 6: Creates s. 641.394, F.S., relating to fail-first protocols.

Section 7: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   According to AHCA, the provisions related to the override of step-therapy and fail-first protocols and the plans having to continue to pay for some drugs after removal from the PDL could increase costs to the Medicaid program. AHCA has concluded the fiscal impact is indeterminate, but likely to be significant.[42] Similarly, the requirement that AHCA pay for all newly-approved drugs without prior authorization until considered by the P&T Committee will likely significantly increase the cost of the prescription drug benefit.

   AHCA is required to pay actuarially sound, risk-adjusted rates[43] to the managed care plans participating in the MMA program. To the extent the provisions of the bill increase the cost of the prescription drug benefit to the MMA plans, these costs will be passed on to the state through required increases in the rates paid to the plans. The bill requires HMOs to pay claims of people who have Medicaid identification cards, regardless of whether the recipient is actually eligible at the time of service. This will likely significantly increase Medicaid costs.

[41] Information obtained from representatives of the health insurance industry on 03/21/2014, on file with staff of the Insurance & Banking Subcommittee.
[42] 2014 Agency Legislative Bill Analysis of HB 1001, AHCA, February 21, 2014.
[43] S. 409.968, F.S. and 42 CFR §438.6(c)(2).

The State Group Insurance Program is projected to spend $1.3 billion on medical claims[44] in FY 2014-15 and is projected to spend $487 million on pharmacy claims[45] in FY 2014-15.[46] To the extent the provisions of the bill increase the cost of the prescription drug benefit, the State Group Insurance Program will incur increased costs. Likewise, the provisions disallowing retroactive claims denial because of an incorrect authorization or the possession by a subscriber of an identification card will cause the State Group Insurance Program to incur increased costs for medical claims.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill's provisions relating to the payment of claims and step-therapy are likely to increase costs for the plans and the employers and consumers who receive services. Because of the current law regarding grace periods for HMOs and health insurers, the prohibition on retroactive denial of claims will result in plans having to pay claims when the subscriber or policyholder was, in fact, ineligible.

Although there are studies which indicate that some step-therapy programs result in patient non-compliance and ineffective treatment, the provisions in the bill relating to step-therapy will likely increase overall costs, because the bill not only limits the application of step-therapy, it allows, in some cases, the circumvention of existing protocols.[47]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to: require counties or municipalities to spend funds or take an action requiring the expenditure of funds; reduce the authority that counties or municipalities have

[44] HMO medical costs are projected to increase 8% in FY 2014-15 and 8% in FY 2015-2016. PPO medical costs for are projected to increase 7.5% for FY 2014-2015 and 7.5% for FY 2015-16.

[45] Costs for the HMO pharmacy benefit are projected to increase 8.6% in FY 2014-15 and 10.5% in FY 2015-2016. Costs for the PPO pharmacy benefit are projected to increase 6.3% for FY 2014-2015 and 10.5% for FY 2015-16.

[46] State Employees' Group Health Self-Insurance Trust Fund, Report on the Financial Outlook, March 4, 2014. Available at: http://edr.state.fl.us/Content/conferences/healthinsurance/HealthInsuranceOutlook.pdf

[47] One of the most recent discussions on the costs associated with step therapy occurred on December 18, 2013 at the meeting of the Pension & Health Benefits Committee of the California Public Employees' Retirement System (CalPERS). Material for Agenda Item 8 states, "As of 2011, 14 evaluations of step therapy programs have been published. Five therapy classes were evaluated, including antidepressants, antihypertensives, antipsychotics, nonsteroidal anti-inflammatory drugs and proton pump inhibitors. Research demonstrates that step therapy programs for all therapy classes but antipsychotics can provide significant drug savings. The drug cost savings result from greater use of generics, and to a lesser extent, a decrease in use of medications. In addition, findings conclude that step therapy programs did not impact utilization of hospitals and emergency rooms. Further research to evaluate the impact of step therapy programs on cost savings and clinical outcomes is recommended for other drug therapy classes." Available at www.calpers.ca.gov/eip-docs/about/committee.../item-8.pdf (last viewed on March23, 2014).

to raise revenues in the aggregate; or reduce the percentage of a state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None provided by the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES